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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,006	09/05/2003	Christine Dingivan	10271-116-999	3565
20583	7590	10/10/2007		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER SKELDING, ZACHARY S	
			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			10/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/657,006

Applicant(s)

DINGIVAN ET AL.

Examiner

Zachary Skelding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9-25-06 7-18-07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 45-82 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Applicant's amendment to the claims of September 25, 2006 and applicant's remarks filed July 18, 2007 are acknowledged.

Claims 1-44 have been canceled.

Claims 45-82 have been added.

Claims 45-82 are pending.

2. This Office Action is in response to applicant's amendment to the claims of September 25, 2006 and applicant's remarks filed July 18, 2007.
3. In the election of species filed July 21, 2006 applicant elected that the following species be examined on the merits: the anti-CD2 antibody is "MEDI-507" and "an anti-CD2 antibody with the proviso that said antibody is NOT MEDI-507" but it has the same properties as MEDI-507; the type of cancer is "peripheral T-cell lymphoma"; the type of experimental therapy is "aggressive combination chemotherapy"; the therapeutic agent or drug conjugated to antibody is "auristatin PHE" and the cancer therapeutic is "cyclophosphamide".

It is noted that claims 14 and 15, as originally presented and examined in the first Office Action on the merits of this application mailed October 24, 2006, were generic claims drawn to a method of treatment "wherein the T-cell malignancy is...a peripheral T-cell neoplasm," or "wherein the T-cell malignancy is...a peripheral T-cell lymphoma...or an anaplastic large cell lymphoma."

It is further noted that original claim 16, which was indicated as withdrawn by applicant in their election of July 21, 2006 and not examined in the first Office Action on the merits of October 24, 2006, was also a generic claim drawn to a method of treatment "wherein the T-cell malignancy is not a cutaneous T-cell lymphoma."

However, with applicant's cancellation of all previously pending claims and the addition of new claims 45-82 in the amendment filed March 26, 2007, applicant has presented new claims that are not generic like original claims 14 and 15 but instead are drawn to methods of treating *particular species* of T-cell malignancies not previously examined, namely "adult T-cell leukemia"(claim 79) and "large granular lymphocyte leukemia." (claim '80).

Due to the introduction of new claims that read on particular species of disease not previously elected as species of disease to be examined, applicant has necessitated the Supplemental Species Election requirement set forth below.

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It is further noted that the claims as originally presented and examined in the first Office Action on the merits of October 24, 2006 read on “a method for treating or ameliorating a T cell malignancy” (e.g., claim 8) or “a method for treating or ameliorating a T cell malignancy wherein the patient had previously been treated by the administration of...standard...therapies...but not by...MEDI-507” (e.g., claim 31).

However, with applicant's cancellation of all previously pending claims and the addition of new claims 45-82 in the amendment filed March 26, 2007, applicant has presented new claims drawn to patentably distinct species of “a method for treating or ameliorating a T cell malignancy” that were not previously presented or particularly examined, namely “a method of treating a T cell malignancy refractory or non-responsive to chemotherapy” (e.g., claim 47) and “a method of treating a T cell malignancy wherein the human has not previously been treated for the T-cell malignancy” (e.g., claim 68).

Due to the introduction of these new claims encompassing species of inventions not previously examined applicant has necessitated the supplemental species election requirement set forth below.

#### ***Supplemental Species Election***

4. This application contains claims directed to the following patentably distinct species of peripheral T cell lymphomas, for example: “wherein the T cell malignancy is adult T-cell leukemia” OR “wherein the T cell malignancy is large granular lymphocyte leukemia” OR “wherein the T cell malignancy is angioimmunoblastic T-cell lymphoma” OR “wherein the T cell malignancy is intestinal T-cell lymphoma”. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 45-82 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. This application contains claims directed to the following patentably distinct species: "a method of treating a T cell malignancy refractory or non-responsive to chemotherapy" and "a method of treating a T cell malignancy wherein the human has not previously been treated for the T-cell malignancy". The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.  
Patent Examiner  
September 27, 2006



MICHAIL BELYAVSKYI, PH.D.  
PATENT EXAMINER

10/01/07